

RECEIVED  
CENTRAL FAX CENTER

MAR 09 2004

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

OFFICIAL

In the application of:

Katsuya DAIMON et al.

Serial No.: 09/548,717

Filing Date: April 13, 2000

For: METHOD OF EXTRACTING NUCLEIC  
ACIDS USING PARTICULATE  
CARRIER

Examiner: S. Chunduru

Group Art Unit: 1637

REQUEST FOR RECONSIDERATIONMail Stop AF Amendment  
Commissioner for Patents  
2011 South Clark Place  
Room 1B03, Crystal Plaza 2  
Arlington, VA 22202

Dear Sir:

Applicant requests reconsideration of the examiner's refusal to enter the amendment filed January 9, 2004. The Advisory Action dated February 4, 2004 indicates, at box 2, that the proposed amendments would not be entered because "they raise new issues that would require further consideration and/or search." No further explanation is given. At box 5, the Advisory Action indicates that the amendment "has been considered but that it does not place the application in condition for allowance because: Amendment is not entered." Emphasis in original.

Applicant respectfully requests entry and consideration of the Amendment filed January 9, 2004 because it does not raise any new issues, and because it places the application in a condition for allowance.

The only amendment to the claims proposed in Applicant's January 9, 2004 submission is the following:

1. (currently amended) A method of extracting nucleic acids from a material containing nucleic acids using a nucleic acid-binding particulate carrier which contains silica or its derivative, the method ~~comprising essentially consisting of~~ the steps of:

(a) mixing the material containing nucleic acids, a nucleic acid-binding particulate carrier having a particle diameter of 0.5 to 15.0  $\mu\text{m}$ , a pore diameter of 80 to 250 nm and a pore volume of 0.2 to 5 ml/g, and a nucleic acid extraction solution for allowing the nucleic acids to adsorb to the particulate carrier, to thereby bind the nucleic acids to the particulate carrier, the nucleic acids being bound to the silica particulate carrier via hydrogen bonds formed between hydroxyl groups of silica of the particulate carrier surfaces ~~on the particle surfaces of the carrier~~ and bases of the nucleic acids;

(b) separating a composite of the nucleic acids and the particulate carrier from the mixture obtained in Step (a) to remove contaminants; and

(c) eluting and collecting the nucleic acids from the composite of the nucleic acids and the particulate carrier.

This amendment raises no new issues. Indeed, Applicant respectfully submits that this amendment is directly responsive to **an issue that was raised by the examiner**. Applicant submits further that it has *twice* tried to amend the claim to address the issue as it was presented by the examiner. Refusal to enter the subject amendment under these circumstances is manifestly unfair to Applicant, but it is especially unreasonable given that in the first two office actions in this case, the primary prior art rejections were groundless, leading to a premature final action and the filing of an RCE. A brief history of the relevant portions of the prosecution of this application follows:

In the first office action on the merits, dated January 16, 2002, the examiner rejected claims 1-22 as anticipated by Uematsu, et al. This rejection was groundless. On April 12, 2002, Applicant filed an Amendment and response, pointing out that Uematsu does not disclose the pore diameter required by the claims.

On July 3, 2003, a further office action issued in which the §102 rejection over Uematsu was withdrawn and replaced with a §103 rejection over Uematsu in view of Yamauchi. This rejection was groundless because there was no motivation to combine these references. Nevertheless, the office action was made final. On December 3, 2003,

Applicant filed an amendment adding a new claim and requesting reconsideration of the outstanding rejection on the grounds that there is no motivation to combine Uematsu and Yamauchi because the references actually teach away from one-another.

On December 24, 2003, a first Advisory Action issued indicating that the amendment would not be entered because the new claim introduced limitations that had not previously been considered. The Advisory Action did not address the lack of motivation for the Uematsu/Yamauchi combination.

On January 29, 2003, Applicant filed a Request for Continued Examination (RCE) requesting entry of the December 24, 2003 amendment.

On February 25, 2003, a further office action issued in which the rejection of most of the claims over the Uematsu/Yamauchi combination was withdrawn and replaced with a §102 rejection over Yamauchi alone (previously, the secondary reference). In support of this rejection, the examiner alleged that according to Yamauchi, "nucleic acids bind to the silica particulate via hydrogen bonds between hydroxyl groups **on the particle surfaces of the carrier.**" Emphasis added.

In response, Applicant amended claim 1 (Amendment dated May 27, 2003) to specifically recite "the nucleic acids being bound to the silica particulate carrier via hydrogen bonds formed between hydroxyl groups on the particle surfaces of the carrier and bases of the nucleic acids." In the remarks section, Applicant argued that

Claim 1, as amended herein, requires that extraction of nucleic acids occur by the binding of the nucleic acids to the silica particulate carrier via hydrogen bonds between 1) hydroxyl groups **on the surface of the carrier** and 2) bases of the nucleic acids." Emphasis added.

Applicant pointed out that, in contrast, that

Yamauchi does not disclose hydrogen bonding between the nucleic acids and the silica particle, because **all available binding sites on the silica particle** are occupied by the coupling agent.

On October 9, 2003, a second final action issued, maintaining the rejection over Yamauchi (the outstanding final office action). The examiner maintained the rejection over Yamauchi, even in the face of Applicant's amendment, on the grounds that the

*acrylamide* of Yamauchi (the coupling agent to which the nucleic acids are bound) "is on the surface of the carrier."

The amendment at issue was a direct response to the examiner's contention that the acrylamide of Yamauchi is "on the surface of the carrier." That is, the present amendment is intended only to make even more clear what Applicant had intended with the previous amendment, i.e., that the hydrogen bonding recited in the claim occurs between the nucleic acids and the particulate carrier itself, **and not the coupling agent**. This was the intention of the Amendment made on May 27, 2003, and this is the purpose of the presently proposed amendment. Accordingly, the proposed amendment raises no new issues.

Moreover, Applicant presumes that the examiner has performed a proper search and that the art of record is the closest available prior art. Since the proposed amendment *clearly avoids* the teachings of the art of record, the proposed amendment *prima facie* places the application in a condition for allowance.

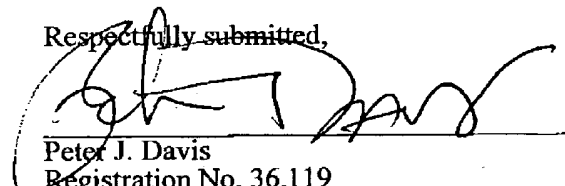
In view of the foregoing, reconsideration of the refusal to enter the proposed amendment is respectfully requested.

In the event that the transmittal letter is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing 472552000100.

Date: March 9, 2004

By:

Respectfully submitted,

  
Peter J. Davis  
Registration No. 36,119  
Morrison & Foerster LLP  
1650 Tysons Blvd, Suite 300  
McLean, VA 22101  
Telephone: (703) 760-7748  
Facsimile: (703) 760-7777

